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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,708	06/02/2005	Yasunori Shiraki	707550.000250	6556
29540 7590 03/17/2011				
DAY PITNEY LLP				
7 TIMES SQUARE				
NEW YORK, NY 10036-7311				
EXAMINER				
DINH, BACH T				
ART UNIT		PAPER NUMBER		
1724				
NOTIFICATION DATE		DELIVERY MODE		
03/17/2011		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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# Office Action Summary

**Application No.**

10/537,708

**Applicant(s)**

SHIRAKI ET AL.

**Examiner**

BACH T. DINH

**Art Unit**

1795

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 January 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12, 14-17, 19 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-12, 15-17, 19 and 21-23 is/are rejected.
- 7) ☒ Claim(s) 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Continued Examination Under 37 CFR 1.114**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/27/2011 has been entered.

### **Summary**

2. This is the response to the communication filed on 01/27/2011.
3. Claims 1-12, 14-17, 19 and 21-23 remain pending in the application.
4. Claim 1-12, 15-17, 19 and 21-23 are rejected.
5. Claim 14 is objected.

### **Claim Rejections - 35 USC § 102**

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-12, 15-17 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Charlton (US 6,960,287) with further evidence provided by Oura et al. (US 2006/0042942).

Charlton is cited and relied on for the first time in this office action. Its use is necessitated by Applicant's amendment to the claims.

Independent claim 1 recites "an analytical tool to be mounted to an analytical apparatus" and subsequent dependent claims recite "the analytical tool". Therefore, patentability of the analytical tool is determined based on the structure of the analytical tool itself and not the way in which the analytical tool is mounted to the analytical apparatus or the structures of the analytical apparatus or the effects on the analytical tool when the analytical tool is mounted to the analytical apparatus.

Addressing claims 1-2, Charlton discloses an analytical tool (figures 1-3), comprising:

A substrate 12 includes a first end edge opposite a second end edge and a first longitudinal edge opposite the second longitudinal edge (figure 1);

A plurality of electrodes 16 and 18 formed on the substrate (figure 1, 3:15-28) extending between the first end edge and the second end edge; and

A reagent portion 26 formed on the substrate adjacent the first end edge of the substrate (figures 1-2, 3:29-43);

Wherein at least one of the electrodes serves as a disturbing-noise countermeasure electrode to which disturbing noise is more likely to come in comparison with the electrode other than said at least one of the electrodes (the terminal 32 of electrode 18 is exposed as seen in figure 1; Oura discloses a blood glucose sensor (figure 7); wherein, the electrodes 81 and 82 are exposed in the flow channel and at the terminal ends 91 and 92, respectively (figure 7). Furthermore, the exposed portion are subjected to static

electricity when the test strip 8 is mounted manually into the measuring apparatus 9 [0003-0005]; therefore, in the biosensor of Oura the exposed portions of the electrodes 81, 82 in the flow channel and at the terminal ends 91 and 92 are the noise inputting exposed portion for allowing input of static electricity; thus, the evidence by Oura shows that the exposed portions of the electrode 18 of Charlton for contacting the analyte and at the terminal end are structurally capable of allowing the input of static electricity or disturbing noise; hence, the electrode 18 of Charlton is structurally equivalent to the claimed disturbing-noise countermeasure electrode and the exposed portions of the electrode 18 are the noise inputting exposed portion as claimed), the electrode 16 serves as the working electrode;

Wherein the electrode 18 of Charlton includes a first exposed end, a first main line portion, a second main line portion and the third main line portion as required by current claim (please see figure 1);

Wherein the working electrode includes a second exposed end 30 located adjacent to the second end edge and extends from the second exposed end toward the first end edge between the first and third main line portions of the disturbing-noise countermeasure electrode (figures 1-2);

Wherein the reagent portion 26 bridges between the working electrode 16 and the second main line portion of the disturbing noise countermeasure electrode (figure 2).  
With respect to the limitation “an analytical apparatus which includes a plurality of terminals and an analysis circuit”, as stated above, patentability of the analytical tool is determined based on the structure of the analytical tool itself and not the way in which

the analytical tool is mounted to the analytical apparatus or the structures of the analytical apparatus or the effects on the analytical tool when the analytical tool is mounted to the analytical apparatus. However, even if the above limitation is given full consideration, Charlton discloses the analytical tool 10 is mounted to a meter (3:29-43); therefore, Examiner takes official notice that the meter of Charlton must include a plurality of terminals for contacting the electrodes of the analytical tool and an analysis circuit for processing the measured current from the analytical tool.

Addressing claims 3-4, the subject matter of current claims are directed to the electrical connection when the analytical tool is mounted to the analytical apparatus. The analytical apparatus is only what the applicant intends to mount to the analytical tool according to the preamble of claim 1, so limitations drawn to how the analytical tool interacts with the unspecified and unclaimed analytical apparatus do not further structurally define the analytical tool itself.

Addressing claim 5, electrode 16 is the working electrode, electrode 36 is the second electrode and electrode 18 is the third electrode serves as the disturbing-noise countermeasure electrode (figure 1).

Addressing claims 6-7, the subject matter of current claims are directed to the electrical connection when the analytical tool is mounted to the analytical apparatus. The analytical apparatus is only what the applicant intends to mount to the analytical tool

according to the preamble of claim 1, so limitations drawn to how the analytical tool interacts with the unspecified and unclaimed analytical apparatus do not further structurally define the analytical tool itself.

Addressing claim 8, the electrode 16 is the working electrode, electrode 18 is the second electrode and electrode 36 is the third electrode. Furthermore, electrode 18 is the disturbing-noise countermeasure electrode as stated above. Moreover, the electrode 36 is also exposed to the flow channel; therefore, the electrode 36 is structurally capable of serving as the disturbing-noise countermeasure electrode according to the evidence provided by Oura as stated above.

Addressing claims 9-10, the subject matter of current claims are directed to the electrical connection when the analytical tool is mounted to the analytical apparatus. The analytical apparatus is only what the applicant intends to mount to the analytical tool according to the preamble of claim 1, so limitations drawn to how the analytical tool interacts with the unspecified and unclaimed analytical apparatus do not further structurally define the analytical tool itself.

Addressing claim 11, Charlton discloses a flow path 58 (figure 3), and an air vent 52 (figure 3).

Addressing claim 12, the electrode 18 is exposed to the outside via the flow path 58 and the air vent 52; therefore, the exposed portion of the electrode 18 in the flow path is the noise inputting exposed portion is exposed through the air vent (figure 3).

Addressing claims 15-16, the lid 56 is the cover in which the air vent is formed and the exposed portions of the electrode 18 are located at a periphery and surround the air vent (figure 3).

Addressing claim 17, please see figures 1-3.

Addressing claim 19, the limitation of current claim is drawn to the process of mounting the analytical tool to the analytical apparatus. The analytical apparatus is only what the applicant intends to mount to the analytical tool according to the preamble of claim 1, so limitations drawn to how the analytical tool interacts with the unspecified and unclaimed analytical apparatus do not further structurally define the analytical tool itself.

### **Claim Rejections - 35 USC § 103**

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.



9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claim 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton (US 6,960,287) in view of Rappin et al. (US 6,572,745) with further evidence provided by Oura et al. (US 2006/0042942).

Addressing claim 21, Charlton is silent regarding a pinch portion.

Rappin discloses a biosensor; wherein, the side of the biosensor 310 has contour portions or claimed pinch portions located at the sides of the body (figure 13, 11:45-48).

At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the biosensor of Charlton with the contour portions on the biosensor body like that of Rappin because the contour portions allow easy insertion of the biosensor to the meter (Rappin, 11:45-48).

11. Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton (US 6,960,287) in view of Rappin et al. (US 6,572,745) as applied to claim 21 above, and further in view of Tokunaga et al. (US 2003/0175946).

Addressing claims 23-23, Rappin discloses the pinch portion comprises a recess formed on the longitudinal edges of the substrate (figure 13). Therefore, in the modified test strip

of Charlton, the pinch portion would also comprise the recess formed each of the first and second longitudinal edges of the substrate as required by claim 23. Furthermore, Charlton discloses the spacer 54 covering electrode 18 except for the exposed portion in the flow path 58, which is also adjacent to the longitudinal edges of the substrate (figure 3) for the word "adjacent" is interpreted to include the definition "being near or close". Charlton is silent regarding the spacer is insulative.

Tokunaga discloses a biosensor comprises an insulating spacer 6 [0044].

At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the analytical tool of Charlton with the insulating spacer of Tokunaga because substituting the known insulating spacer of Tokunaga for the spacer of the known analytical tool of Charlton to achieve the predictable result of forming the flow path for the biosensor is a matter of obviousness (rationale B, KSR decision, MPEP 2141). Furthermore, the insulating spacer would provide electrical insulation between the electrodes 16 and 18 of Charlton.

#### **Allowable Subject Matter**

12. Claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter:

Claim 14 recites the insulating film includes an opening for partially exposing the island provided directly below the air vent. Figure 3 shows the exposed portion of the electrode 18 in the flow path; however, the exposed portion is not the island that is provided directly below the air vent. Furthermore, Charlton is silent regarding the spacer 54 being insulative; however, insulative spacer is a well known element in the art of biosensor. Without explicit teaching from the prior art, one with ordinary skill in the art would not have found it obvious to modify the electrode 18 to include an island that is provided directly below the air vent because the electrode 16 is provided directly below the air vent; thus any modification would require the relocation of the electrode 16. Therefore, the prior art does not disclose nor suggest the disturbing-noise countermeasure electrode includes an island provided directly below the air vent in order to input the noise as required by the cumulating limitation of claims 1, 11-12 and 14.

#### **Response to Arguments**

14. Applicant's arguments with respect to claims 1-12, 14-17, 19 and 21-23 have been considered but are moot in view of the new ground(s) of rejection.

Charlton is cited and relied on for the first time in this office action to show that an analytical tool comprises the disturbing-noise countermeasure electrode includes a first exposed end, a first main line portion, a second main line portion and a third main line portion configured in the manner as claimed is already disclosed in the prior art. Thus, as discussed above, the amended claim 1 is anticipated by the disclosure of Charlton.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BACH T. DINH whose telephone number is (571)270-5118. The examiner can normally be reached on Monday-Friday EST 7:00 A.M-3:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on (571)272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/  
Supervisory Patent Examiner, Art Unit 1753

BD  
03/09/2011

